

# Exhibit 57

## Center for Regulatory Effectiveness

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Submitted via mail and also via email to [cirinfo@cir-safety.org](mailto:cirinfo@cir-safety.org)

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Initial Comments on CIR draft Scientific Literature Review  
For “Talc as Used in Cosmetics”  
(posted by CIR Aug. 22, 2012)

Dear Dr. Andersen,

We commend CIR staff for the thoroughness of the draft SLR. We do have a number of comments aimed at improving the evaluation. Most of our comments pertain to the extensive ovarian and endometrial cancer epidemiology, since we agree with the draft that the non-epidemiologic evidence indicates lack of talc carcinogenicity (*e.g.*, the use of talc in pleurodesis and pharmaceuticals and the fairly extensive *in vitro* and *in vivo* experiments).

The Center for Regulatory Effectiveness is not representing a particular company or industry segment in filing these comments. CRE operates independently and these comments are solely its own. CRE has become involved in this issue because it could impact not just the cosmetics industry, but also many other diverse and important industries that use talc in their products. If further support for the notion that talc causes cancer (irrespective of target organ) emerges, even in the form of a CIR evaluation of the data as insufficient to determine safety, it could put pressure on companies to find substitutes. It appears that this has already happened to a large extent in the cosmetics industry, where many companies now advertise that their products are talc-free, apparently due to a plethora of Internet comments that talc causes cancer and earlier publicity about the various epidemiologic studies and discovery of asbestos contamination in some brands of talcum powder during the 1970s.

To start, a significant issue is whether the subjects in the epidemiologic studies could have been exposed to brands of body powder contaminated with asbestos, thereby distorting the results as they would pertain to cosmetically pure talc as defined in the U.S. since 1976.

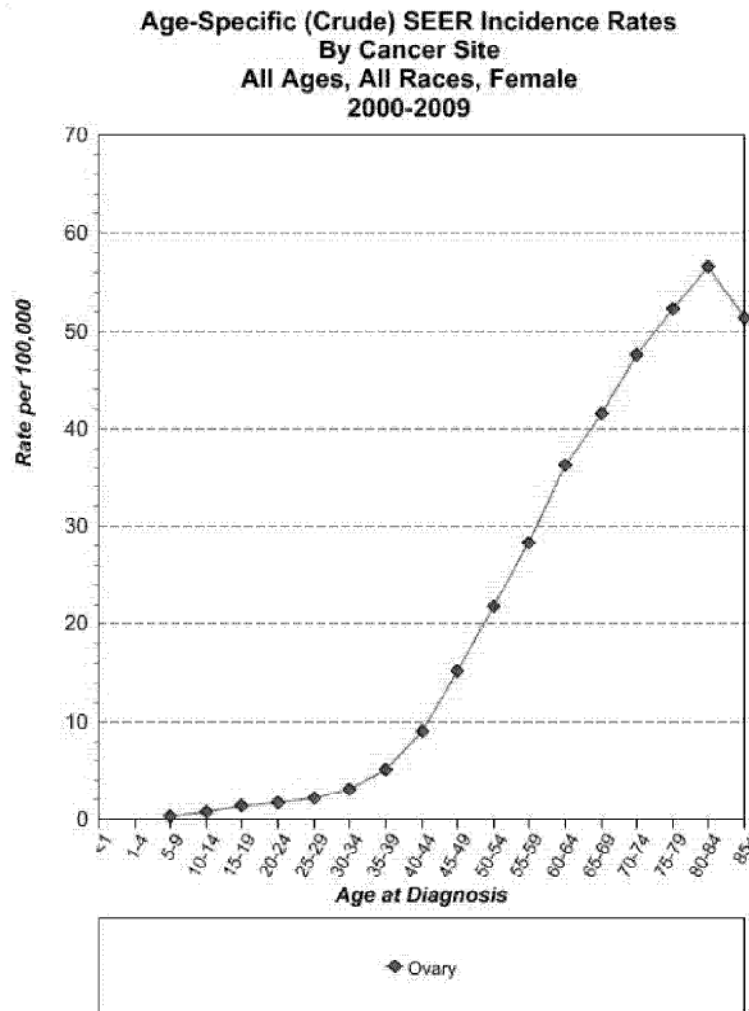
### **Potential exposure of study subjects to talcum powder contaminated with asbestos prior to about 1976**

The very first paragraph of the draft SLR recognizes the possibility that some brands of talc were contaminated with asbestos prior to about 1976, and it states that therefore “studies

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before that date are likely of uncertain relevance to talc as currently used in cosmetics.” But this is not the point that should be made. The issue is not whether studies prior to 1976 are relevant; the issue is whether subjects in the epidemiologic studies were significantly exposed to pre-1976 talc.

In examining this issue it should first be recognized that ovarian cancer is primarily a late-age cancer. From 2005-2009, the median age at diagnosis for cancer of the ovary was 63 years of age.<sup>1</sup> The following graph shows the age-specific incidence rates most recently reported by SEER (the NCI Surveillance Epidemiology and End Results program). This graph was created by us from tools on the SEER website.<sup>2</sup> As can be seen, the rates per 100,000 population continue to rise substantially from the median of 63 until age 84.



Cancer sites include invasive cases only unless otherwise noted.  
Incidence source: SEER 18 areas (San Francisco, Connecticut, Detroit, Hawaii, Iowa, New Mexico, Seattle, Utah, Atlanta, San Jose-Monterey, Los Angeles, Alaska Native Registry, Rural Georgia, California excluding SF/SJM/LA, Kentucky, Louisiana, New Jersey and Georgia excluding ATL/RG).  
Rates are per 100,000.  
Ovary excludes borderline cases or histologies 8442, 8451, 8462, 8472, and 8473.  
Datapoints were not shown for rates that were based on less than 16 cases.

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Thus, for example, if we assume that many subjects first began using talcum powder at about the age of 20 (which might be conservative given the data on first use at <20 in Rosenblatt *et al.* 2011 and in Harlow *et al.* 1992), that would mean that, applying the SEER 63 yr. median, a large portion of the ovarian cancer cases in the studies started using talcum powder 43 years before the time they were interviewed about use (or perhaps close to the time of diagnosis). That would mean that even a case interviewed in 2005 (apparently the latest interview year in the epidemiology), for example, could well have begun using talcum powder in 1962 or thereabouts, far before the 1976 “cut-off” suggested in the first paragraph of the draft SLR and at a time when there could have been a high likelihood of exposure to asbestos in some brands of powder.

A review of the full spectrum of individual epidemiologic studies confirms the likelihood of substantial pre-1976 exposure in the subjects. The CRE Table 1 below shows dates of interview or diagnosis and the reported ages of the subjects. (Note that many of the studies reported a mean age, whereas the SEER data above are based on median age.) For example, note that a number of studies used the 1982 Nurses Health Study (“NHS”) questionnaire (1982 was the only year in which the questionnaire contained a question on talc use), which would have meant that presumably most of the subjects responding to the relevant question in 1982 would have used predominantly pre-1976 talcum powder.

**Table 1. Potential exposure of subjects to asbestos contamination prior to about 1976**

Study (chronolog.)	Study yr(s)/yr(s) Subjects questioned (or date of diagnosis)	Case subject age range (median or mean) at diag. or interview	Study location/comments
Cramer et al. 1982	1978-81	18-80 (mean 53.2)	U.S. (Greater Boston area)
Hartge et al. 1983	1974-77	No info.	U.S. (Wash., DC area)
Whittemore et al. 1988	(diag. 1983-85)	18-74	U.S. (San Francisco area)
Booth et al 1989	1978-83	20-64 (mean 52.4)	England (London, Oxford)
Harlow & Weiss 1989	(diag. 1980-85)	20-79	U.S. (western Wash. State)
Harlow et al. 1992	(diag. 1984-87)	18-76 (59% ≥50)	U.S. (Boston area)
Rosenblatt et al. 1992	(diag. 1981-85)	Most 40-69	U.S. (Baltimore hospital)
Hankinson et al. 1993	1982 (NHS)	36-61	U.S. (NHS --prospective, but small numbers – n. not given)
Tzonou et al. 1993	(diag. 1989-91)	No info.	Greece (only 6 exp. cases)
Purdie et al. 1995	(diag. 1990-93)	18-79 (most >40)	Australia
Shushan et al. 1996	1990-93	36-64	Israel – fertility drug study
Chang & Risch 1997	(diag. 1989-92)	35-79 (57.2- mean?)	Canada (Toronto area)
Cook et al 1997	(diag. 1986-88)	20-79 (majority 55-79)	U.S. (western Wash. State)
Green et al. 1997	(diag. 1990-93)	18-79	Australia
Godard et al. 1998	(diag. 1995-96)	26-85 (53.7 mean at diag.)	Canada (Montreal)
Cramer et al. 1999	(diag. 1992-97)	maj. >50	U.S. (E. Mass. & NH)
Wong et al. 1999	(diag. 1982-95)	54.9 mean	U.S. (Buffalo, NY- Roswell)

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Gertig et al. 2000	1982 (NHS)	36-61	U.S. (NHS prosp. cohort)
Ness et al. 2000	1994-98	20-69	U.S. (PA, NJ, DE)
Mills et al. 2004	2000-2001	<40 - ≥70 (mean 56.6)	U.S. (Central California)
Cramer et al. 2005	1998-2003	<35 - ≥65 (subst. ≥65)	U.S. (E. Mass & NH)
Jordan et al. 2007	(diag. 2002-05)	no info.	Australia
Gates et al. 2008	1982 (NHS), 1992-97, 1998-2003 (NECC)	NECC mean 52, NHS mean 61	U.S. (NHS and NECC – E. Mass. & NH)
Merritt et al. 2008	(diag. 2002-05)	<50 - ≥70	Australia
Moorman et al. 2009	1999-2008	20-74 (predom. >50)	U.S. (N. Car.)
Wu et al. 2009	(diag. 1998-2002)	18-74 (predom. >45)	U.S. (Los Angeles County)
Karageorgi et al. 2010	1982 (NHS)	36-61 (48 mean?)	U.S. (NHS, endom. cancer)
Rosenblatt et al. 2011	(diag. 2002-05)	35-74 (subst. no. reported First use at <15 and sig. no. before 1959 or 1970)	U.S. (western Wash. State)
Vitonis et al. 2011	(diag. 1998-2008 – NECC)	Mean 52? (see Gates et al.)	U.S. (NECC - E. Mass. & NH)
Kurta et al. 2012	(diag. 2003-08)	<30-≥70	U.S. (Buffalo, Cleveland, Pittsburgh)
Neill et al. 2012	2005-2007	Mean 61.3 (sig. no. used >40-60 yrs.)	Australia (endom. cancer – contradicts Karageorgi et al.)

**Other Indefiniteness of Substance(s) Exposures in the Epidemiologic Studies**

In 2000, the United States National Toxicology Program (“NTP”) began a review of a nomination of talc for inclusion in the Report on Carcinogens (“RoC”). (The three core Federal agencies of the NTP are NIH/NIEHS, FDA, and NIOSH/CDC, with other agencies such as EPA, CPSC, and DoD participating through the NTP Executive Committee). In 2000, after the NTP RoC Subcommittee of its Board of Scientific Counselors voted 8-2 against listing in the RoC, NTP decided to defer the talc nomination pending further review. After that internal review, in 2005, NTP announced that it was withdrawing both talc nominations (cosmetic talc and occupational exposure to talc) because, it explained: “It has become evident that the literature on both forms of talc, with a few exceptions, provides an inadequate characterization of the actual materials under study to enable one to reach definitive conclusions concerning the specific substances responsible for the range of adverse health outcomes reported.” Although the withdrawal was not accompanied by any further explanation or analysis, a careful review of the epidemiologic studies on talc and ovarian and endometrial cancer shows that, in addition to the asbestos issue discussed above, many of the studies raise obvious questions about the actual exposure that was being studied.

CRE Table 2 below shows that many of the studies were based on questioning of subjects not just about talc, but about any kind perineal exposure to various powders or sprays.



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In addition many of the studies did not quote or characterize the exposure question(s) asked, and they could similarly have been indefinite with regard to talc.

Table 2. Substance studied

Study (chronolog.)	Exposure question to subjects	Comments
Cramer et al. 1982	Exact question not given or characterized.	
Hartge et al. 1983	Exact question not given. Refers to "talc," but also refers to "body powder" near end.	
Whittemore et al. 1988	Exact question not given or characterized.	
Booth et al 1989	Exact question not given or characterized.	
Harlow & Weiss 1989	Exact question not given, but states that women were asked what type(s) of "powders" (also referred to as "talc") they applied to perineum after bathing. Article then states that the responses were then categorized (apparently by the investigators) into one or more of three categories of "talc-containing powders" – baby powder, deodorizing powder, or other or unspecified talcum or dusting powders, or cornstarch.	The study found lack of associations for exclusive use of "baby powder," "combined use," or "talc, unspecified." But in women who used deodorizing powder either alone or in combination with baby powder the RR was significantly higher: 2.8 (1.1-11.7) (n=14).
Harlow et al. 1992	Exact question(s) not given. Article refers consistently to "talc." However, Table 2 refers to use of "generic baby powder" and notes that 7 cases reported use of "combinations of more than one brand," 20 cases reported use of generic baby powder, and 14 cases reported use of "scented powder."	Compared exclusive use pre-1960 with exclusive use post-1960. Pre- was 1.6 (1.1-2.5) (n=75); post- was 1.1 (0.6-2.1) (n=29). Conceded that the study was unable to answer the key question of whether the risk pertains to all cosmetic talcs or only to certain preparations likely to be contaminated with asbestos, and that the difference in risk among pre-1960 and post-1960 users might support the view that purity is the issue.
Rosenblatt et al. 1992	Subjects asked about use of "talc" or "talcum powder"	
Hankinson et al. 1993	Subjects were given 1982 questionnaire for Nurses Health Study ("NHS"), which asked (Q. 29): "Have you <u>ever</u> commonly used talcum, baby powder or deodorizing power" on the perineum or sanitary napkins, daily, 1-6 times per week, or less than once a week.	No statistically significant association found between "talc use" and ovarian cancer, but there were relatively few cases (n not given).
Tzonou et al. 1993	Exact question not given or characterized.	
Purdie et al. 1995	Exact question not given or characterized.	
Chang & Risch 1997	Exact question not given, but article states that subjects were asked about both talc and cornstarch use.	The article also states that "commercial talc substitutes often replace talc with cornstarch."
Cook et al 1996	Exact question not given. Subjects were asked about any or only use of various powders: talcum, cornstarch, baby, deodorizing, scented bath/body, or unspecified. Only 16 of the 99 exposed cases who stated that they used one type of powder exclusively stated that the powder they used exclusively was talcum powder. On the other hand, the vast majority of exposed cases (159) reported use of some powder other than talcum powder or multiple kinds of powders. (Table 4).	Subjects were asked to identify the type of powder they used, and talcum powder was only a small proportion of the different types of "powders." Only 16 out of 99 stated they used talcum powder exclusively; 33 out of 193 (including multiple powder usage) used talcum powder at some time. (See Table 4). Note also that the highest RR was for deodorant spray, which would have raised the overall RR for "powders." Yet, only a few subjects reported using cornstarch-based powder.
Green et al. 1997	Exact question not given or characterized, except for "ever" use of talc.	Article as a whole simply refers to "talc" exposure.

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Godard et al. 1998	Exact question not given or characterized	
Cramer et al. 1999	Subjects were asked whether they “had regularly used talc, baby, or deodorizing powders dusted or sprayed ....”	Article states that only a few subjects reported using cornstarch-based powder.
Wong et al. 1999	Exact question not given or characterized.	
Gertig et al. 2000	Used NHS questionnaire from 1982 (see Hankinson et al. 1993 <i>supra</i> .)	
Ness et al. 2000	“As an adult and prior to [reference date] did you ever use talc, baby or deodorizing powder, at least [frequency and mode].”	Article as a whole refers only to “talc” exposure.
Mills et al. 2004	Exact question(s) not given. Article refers consistently to use of “talc” and “talcum powder.” However, the article also states: “Our study was not able to differentiate between use of perineal powders containing talc and those containing cornstarch ....”	
Cramer et al. 2005	Exact question not given, but this second phase of the New England case-control study (“NECC”) presumably used the same question as the first phase (Cramer et al. 1999, <i>supra</i> ), which asked subjects whether they “had regularly used talc, baby, or deodorizing powders dusted or sprayed ....”	
Jordan et al. 2007	Exact question not given.	
Gates et al. 2008	Exact question not given, but subject population was comprised of the NHS and the first two phases of the NECC. All three studies asked whether the subjects had regularly used “talc, baby, or deodorizing powder, dusted or sprayed.”	
Merritt et al. 2008	Exact question not given, but article states that subjects were asked whether they had ever used “powder or talc” in the genital area.	Article consistently refers to “talc” exposure.
Wu et al. 2008	Subjects asked about “talc use” prior to and after 1975. Exact question(s) not given.	Only pre-1975 use showed an association. Article noted that this was inconsistent with some other studies.
Moorman et al. 2009	Exact question not given.	
Karageorgi et al. 2010	Used 1982 NHS questionnaire. See Hankinson et al. 1993 <i>supra</i> .	Study of endometrial cancer.
Rosenblatt et al. 2011	Subjects asked about use of “powders,” including “talcum, baby, cornstarch, deodorant, body/bath, and other or unknown” prior to and after 1975. But a breakdown by type of powder was not reported, and article narrative states that reporting of use of pure cornstarch powder was “quite uncommon”	“The most frequently reported category of product used after bathing was baby powder (not shown); few women reported exclusive use of talcum powder or of cornstarch (a product that does not contain talcum powder). Within limits of precision, findings regarding ovarian cancer risk among women who reported the use of talcum powder were similar to those presented for all types of powders combined ....” “The validity of all of these studies, including ours, may be influenced by the level of non-response among cases and controls, and by the potential for misclassification (differential and non-differential) of exposure status. The latter derives not just from errors in the recall of the use of genital powder, but from the fact that the presence or concentration of talc can vary from brand to brand and even within one brand of powder over time. Therefore, even when

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		respondents are asked specifically about perineal exposure to powders that contain talc (as in our study), they may be unable to provide accurate information." "Data from additional cohort studies would be welcome, but without details concerning the composition of the powders used by cohort members—details that many participants may not be able to provide—the results of such studies may similarly be ambiguous in their interpretation."
Vitonis et al. 2011	This study involved all three phases of the NECC study, so even though the question(s) asked were not given, it can be presumed that the question(s) in the 3d phase were the same as in the first two phases, in which the question(s) was whether subjects had regularly used "talc, baby, or deodorizing powder, dusted or sprayed." See Cramer et al. 1999 and Cramer et al. 2005, <i>supra</i> .	Article states that subjects were asked about "long term genital talc use."
Neill et al. 2012	Subjects asked whether they had "ever used any sort of powder or talc in the genital area ..."	Endometrial cancer study.

Out of the 23 studies listed in draft SLR Tables 10 and 11 (pp. 73-74), 8 were studies in which the exposure questions, as indicated above, were clearly not specific to talc or talcum powder (Harlow 1992, Ness 2000, Harlow 1989, Cook 1997, Cramer 1999, Cramer 2005, Mills 2004, Merritt 2008). More importantly, out of the 10 studies shown in those tables as reporting weak but statistically significant risk numbers, 5 were ones for which the exposure questions were clearly not specific to talc or talcum powder (Ness 2000, Cook 1997, Cramer 1999, Mills 2004, Merritt 2008). In view of this, the specification in Table 9 (1<sup>st</sup> col.) that the exposure substance in most of the studies was "talc" could be misleading.

One could also well question whether women asked about use of talc or talcum powder really understood that they were being asked about a body powder comprised mainly of the specific mineral talc, rather than simply any smooth, white powder. One is reminded of the days when any photocopying was often referred to as "xeroxing," even after there were many copying machine brands on the market other than Xerox. This could explain the disconnects in the Cook 1997 study with only a small proportion of subjects reporting exclusive use of talcum powder, but few reporting use of cornstarch-based powder, and the Cramer 1999 study reporting little use of cornstarch-based powders. In view of what appears to have been a clear increase in the marketing of cornstarch or other talc-free powders and sprays starting in the 1980s, and a decline in sales of talc-based powders, such low numbers of exposure to cornstarch or other talc-free powders appear very unlikely. In a 1986 commentary, Natow noted that in the wake of the asbestos-in-talc scare in the 1970s, "[m]any consumers switched to powders that were talc-free and contained mainly corn starch."<sup>3</sup> The quoted comments from Rosenblatt 2011 in the above table appear very pertinent. While CRE does not have data on respective market share of various powder compositions, or when compositions changed, and consumer knowledge of constituents, the Personal Care Products Council or its members might be able to provide such data. However, it is apparent from even casual Internet searches since 2000 that there is a great variety of body powders that are being marketed as "talc-free," with many of them noting that they are talc-free due to concerns regarding the potential carcinogenicity of talc.



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**Lack of Evidence Supporting Translocation from Perineum to Ovaries**

A key issue with regard to the epidemiologic studies is whether powder applied externally to the perineum can enter the female reproductive system and translocate to the ovaries (or uterus). If it cannot plausibly do so, there is no basis for assuming exposure of the ovaries to talc, and the epidemiologic studies showing a positive association due to perineal dusting should be disregarded.

A review of the epidemiologic studies shows that many either assumed that translocation can occur (based on statements from other studies), or they relied on several human or animal experiments supposedly showing translocation, detection of talc or talc-like particles in sections of excised human ovarian tissue or ovarian tumors, or reduction in ovarian cancer risk indicated in some studies of women who had undergone tubal ligation or hysterectomy.

**Experimental Studies of Translocation**

None of the experimental studies of particulate translocation, either human and animal, with the exception of the Boorman & Seely NTP rodent study,<sup>4</sup> involved deposition of talc or other dry particulate matter on the perineal skin. The draft SLR does not note this. These studies, summarized below, virtually all involved deposition of solutions containing particulate matter inside the reproductive tract. The Boorman & Seely study was a follow-up to the NTP inhalation rodent bioassay, and the rodents were completely covered with aerosolized talc powder for the duration of the experiment, and no translocation was found (although the anatomy of the rodent reproductive system differs somewhat from that in humans). As discussed in the next section (on anatomic and physiologic barriers), bypassing of the labia minora and most of the vagina is a significant distortion. The administration of oxytocin and anesthesia and elevation of the pelvis were also likely significant distortions of real-world powder application conditions. Use of a solution also likely distorted the experiments, especially those in which a patient had her pelvis elevated. Injection or application via aerosol spray could also have created false conditions. Anesthesia during surgery would likely have impeded muscular peristalsis and ciliatic movement. Administration of oxytocin could induce altered (upward) uterine contractions and anti-paristalsis in the oviducts.

**Table 3. Human and animal experiments in translocation**

Study/experiment	Species	Exposure substance, other conditions	Exposure site	Results
DeBoer 1972	Humans	India ink ("a colloidal suspension of carbon"), 0.2 ml, injected into 159 patients about to undergo abdominal surgery. Cytocinon (synthetic oxytocin) was administered to some. Patients were in Trendelenberg position and placed under anesthesia.	Vagina, cervical canal, or uterus	Patients examined during surgery. Translocation from uterus to fallopian tubes or peritoneum in sign. number; no translocation from cervical canal or vagina, and backflow from uterus. Translocation from vagina to uterus in 2 out of 37.
Egli & Newton 1961	Humans	Suspension of carbon particles in Dextran and bone black, 3-4 ml,	Vaginal posterior fornix	Carbon particles were found in the fallopian

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		placed in the vaginal posterior fornix by speculum. Three patients were undergoing hysterectomy, and the suspension was introduced after anesthesia and oxytocin and with pelvis elevated 15 degrees. After introduction of the suspension, the patients were returned to a supine position.		tubes of 2 out of the 3 women.
Sjösten 2004	Humans	Patients scheduled for hysterectomy. Examined with either cornstarch powdered or non-powdered gloves either 1 or 4 days pre-operatively. Tissue removed during surgery was examined for starch particles.	Vagina	Starch particles found in cervical canal, uterus, fallopian tubes, and peritoneal fluid. Ovaries not mentioned.
Venter & Iturralde 1979	Humans	Radio-labeled human albumin microspheres in solution deposited in patient a day before gyn. surgery. Patients had pelvis elevated for about 2 hr. Count was performed on tissue removed in surgery.	Vaginal posterior fornix	In 9 of 21 cases, radioactivity was detected in the fallopian tubes and ovaries. In 5 there was severe tubal occlusion.
Zervomanolakis 2007	Humans	Deposition of radio-labeled human serum albumin into 1000 patients, followed by administration of oxytocin.	Vaginal posterior fornix	Radioactivity was detected in a large proportion of subjects in the fallopian tubes. Oxytocin greatly increased transport in the follicular phase. The oxytocin apparently assisted peristalsis in the uterus and fallopian tubes.
Boorman & Seely 1994	Rats	Follow-up to NTP inhalation study, in which rodents were exposed to aerosolized talc 6hr/day for <2 yr, resulting in full-body dermal exposure and inhalation	Perineal and pulmonary	No translocation found.
Edelstam 1997	Rabbits	Biosorb™ starch powder deposited intra-vaginally while rabbits were anesthetized and ovulation was induced. Control rabbits used.	Vagina	There was not a statistically significant difference in numbers of particles in all portions of the reproductive tract (excluding ovaries) and the peritoneum. And no adhesions or granulomas were observed. But the authors concluded that translocation ("retrograde migration") could not be excluded.
Henderson 1986	Rats	Talc in saline solution injected into the uterus at the end of the cervical canal in one group, and intra-vaginally in another group	Uterus and vagina	Talc found in ovaries of both groups. Apparently there were no controls, and study is described as a "pilot study."
Keskin 2009	Rats	Talc in saline solution was applied as an aerosol every day for three months to two groups. One group was said to have received intra-vaginal applications, and the other was said to have received perineal applications,	Vagina and perineum(?)	Foreign body reactions, "infections," and increased number of inflammatory cells were found in all portions of the reproductive system. No

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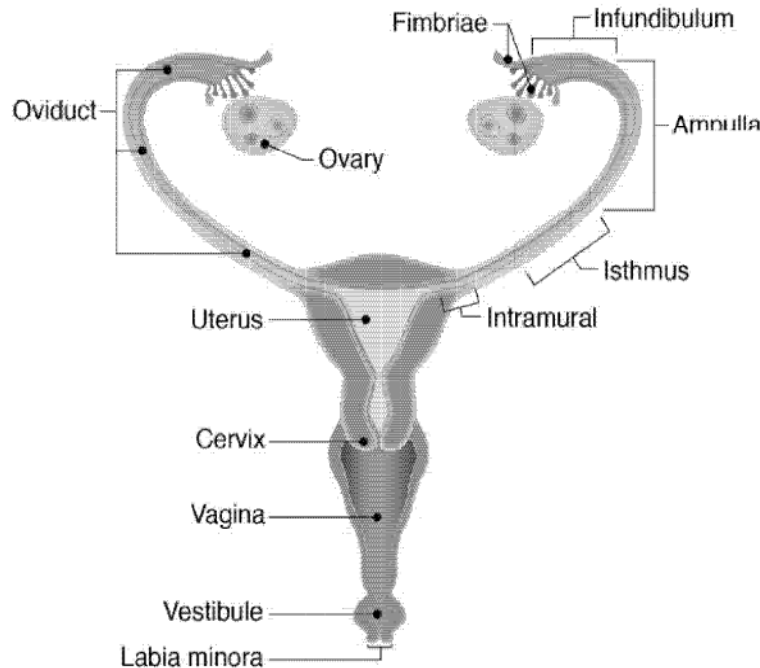
		however the manner in which the "perineal" applications were made via aerosol was not described. Talc in "dust form" was not applied.		neoplastic changes were found. (Translation from Turkish – there appear to be some translation problems -- e.g. statement that the aerosol application "can be optimally intravaginal.") Contradicted by Boorman & Seely, <i>supra</i> .
Phillips 1978	Rabbits	Radio-labeled talc in an aqueous glycerol jelly suspension was injected intra-vaginally into six rabbits (3 for 3 days, 3 for six days, then 3 days to sacrifice)	Vagina	No translocation found in the first group of 3; in the second group, a small amount of radioactivity was found in the cervix and fallopian tubes, but not in the ovaries.
Whener 1985	Monkeys	Neutron-activated talc in water deposited once in posterior fornix of vagina with pelvis elevated 15%. Oxytocin was administered. Animals were sacrificed 1 hr. and 72 hr. after exposure.	Vagina	No translocation found beyond site of deposition. Described as a pilot study. Also used a bone-black solution, but found what seemed to be contamination issues.
Whener 1986	Monkeys	Neutron-activated talc in saline solution injected into the posterior fornix of six monkeys with pelvis elevated 20-25% for 30 workdays. Oxytocin administered 1x/wk.	Vagina	No translocation detected beyond vagina-cervix (dissected as single unit) near site of injection.

### **Anatomic and Physiologic Barriers to Translocation**

Although the draft SLR discusses many of the above translocation experiments, it does not discuss the anatomic and physiologic features of the female reproductive system that are likely to operate as barriers or impediments to intrusion and upward migration (*i.e.*, translocation or retrograde migration) of inanimate particulate matter such as talc from the external perineal skin to the ovaries. The purpose of this section is to discuss those apparent barriers in order to show the lack of biological plausibility for translocation.<sup>5</sup>

The graphic below depicts the complete female reproductive organ system. (The graphic is derived from others in texts noted in the References, since most graphics show only portions of the full system.)

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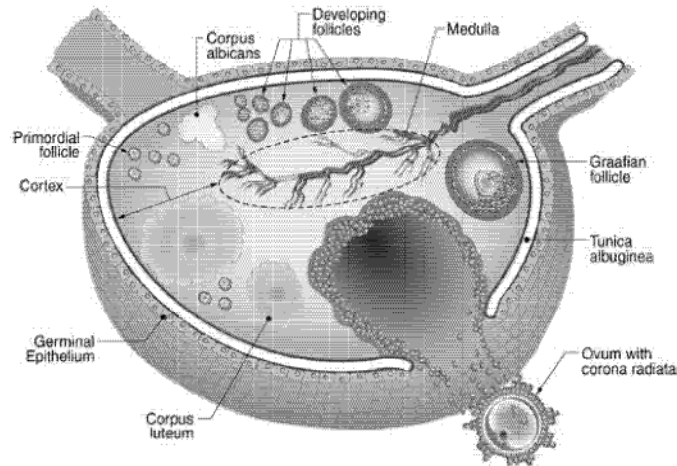
The first thing to consider is that it is not by accident that spermatozoa have a self-contained propulsion system. They have multiple barriers or impediments to overcome. In addition, spermatozoa have, as discussed below, a substantial “headstart” over particulate matter that might be deposited in the external genital area. Spermatozoa are deposited in the vagina, much of it in or near the upper portions of the vagina and the cervical os (mainly in the posterior fornix of the vagina). Such depositions of spermatozoa therefore bypass the labia minora and much of the vagina and its exudates. They are then able to “swim” through the cervical canal (for a short period near ovulation), the uterus, and much of the fallopian tubes. However, even with this means of propulsion, out of the millions or hundreds of millions of spermatozoa normally deposited in the vagina during intercourse, it has been estimated that only roughly several dozen reach the ampulla section of the fallopian tubes where fertilization of an oocyte can usually occur.<sup>6</sup> It is not established whether any spermatozoa travel past the ampulla section of the oviducts and the fimbriae and either enter the peritoneal space or contact the ovaries, except possibly under abnormal conditions. (Note that there is no direct connection between the fallopian tubes and the ovaries – there is open peritoneal space between the fimbriae and the ovaries.)

Ovulation and fertilization occur when a follicle with its included oocyte grows within the ovaries and eventually protrudes through the wall of the ovary and develops into an ovum, and then the ovum breaches the surface of the ovary and escapes along with follicular fluid.<sup>7</sup> (See the depiction of this below.<sup>8</sup>) Note that there is no direct tubal connection between the oviducts and the ovaries that would allow any material to be transported into the ovaries. (The ovaries are attached to the uterus by an ovarian ligament, while another ligament carries the arterial and venous blood.) Through a mechanism that is still unclear (but perhaps signaling by the follicular fluid escaping along with the ovum), the fimbriae sense the ovum and accompanying follicular material when they escape from the ovary and move closer to the



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ovaries and sweep up the oocyte into the fallopian tube where it is propelled by muscular contractions and fluid flowing towards the uterus under the influence of cilia to the ampullary section of the tube, where it can encounter spermatozoa and be fertilized. If an ovum is fertilized, the egg is then propelled towards and into the uterus by tubal peristalsis and oviductal fluid under the influence of the oviductal cilia.<sup>9</sup>



If there is no implantation of the egg into the uterus, the uterine endometrium is regularly sloughed off (approximately every 28 days) and escapes through the cervical canal and vagina as menses.

As should be apparent from this description of the initial phases of reproduction, the movement of reproductive material and fluids is normally away from the ovaries and towards the perineum. All of this movement must be overcome by the propulsive movements of the spermatozoa, with perhaps a temporary assist induced by oxytocin immediately after coitus.

In recent years, evidence has emerged that indicates that during coitus there can be release of oxytocin, and that the oxytocin can temporarily induce reverse peristalsis in the uterus and oviducts in order to assist spermatozoa in reaching the ampulla section of the tubes;<sup>10</sup> however, it is unclear whether this “anti-peristalsis” operates beyond the ampulla region and whether it is sufficiently strong to propel inanimate particulates especially into and past the oviducts. But even if that could happen, the particulate matter would mainly exit into the peritoneal space. And the effectiveness of such a temporary assistive mechanism would depend on the particulate matter initially being present in the uterus. There is also the phenomenon of retrograde menstruation, which could carry particulate matter through the oviducts into the peritoneum, but that also assumes initially the presence of particulate matter in the uterus or oviducts. The transport of uterine endometrium material into the peritoneal cavity can also result in endometriosis.<sup>11</sup>

Following is a list and description of the barriers/impediments to translocation of inanimate particulate matter from the perineum into and through the female reproductive tract to the ovaries under normal conditions.



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1. Closure of the labia minora: Under normal conditions (*i.e.*, not coitus or childbirth), the labia minora are firmly closed by the bulbospongiosus (also known as the bulbocavernosus) sphincter muscles<sup>12</sup> and not even water can enter, much less particulate matter (just like the lips to the oral cavity).<sup>13</sup>
2. Collapsed vagina: Virtually all diagrams of the female reproductive system (even the one above) depict the vagina as an open tube. This is not anatomically accurate. Under normal conditions the vagina is collapsed inward such that it would be seen in cross-section roughly like an H or W (in other words, a potential, rather than actual, space).<sup>14</sup>
3. Vaginal and cervical mucus and exudate: The walls of the vagina and cervix exude mucus and other fluids, which flow downward, with the amount and viscosity varying with menstrual status and age.<sup>15</sup> The Office of Women's Health at the U.S. Dept. of Health and Human Services advises against douching because, as it states on its website, the vagina cleans itself with those secretions.<sup>16</sup>
4. Closed cervical os: Most of the time during the menstrual cycle the entrance to the cervical canal is closed off, much like the vaginal os is closed off by the labia minora.<sup>17</sup>
5. Hostile cervical mucus: During most of the menstrual period the cervical canal is filled with a mucus that is impenetrable even to spermatozoa. For several days during the periovulatory period of the menstrual cycle this mucus becomes more fluid, but it only allows material such as spermatozoa (about 5 microns), and possibly only if it is motile, to pass through.<sup>18</sup>
6. Cervix-to-oviduct length of passage: If material can travel through the cervical canal into the uterus, it still would have to travel some distance to the top of the uterus in order to enter the small openings into the oviducts. The entrance to the oviducts in the uterus is less than a millimeter in diameter.<sup>19</sup>
7. Menses: At the end of each menstrual period (about 28 days), the endometrial surface of the uterus sloughs off and flows out the vagina. This flow likely flushes out with it anything in the way of foreign material in the uterus, cervical canal, or vagina.
8. Oviductal peristalsis: If an ovum is fertilized in the ampulla section of an oviduct, oviductal peristalsis and fluid, assisted by the cilia in the oviducts, move it into the uterus.<sup>20</sup>
9. Fimbrial-ovarian gap: If particulate matter were somehow to travel to the fimbrial section of the oviducts, it would exit into the perineal cavity. At that point, it could go in many different directions and land on the surface of the peritoneum, different organs, including the surface of the ovaries, or the peritoneal lining. If that happened, the particulate matter would immediately be subject to phagocytosis.
10. Ovarian follicular exudate: As follicles develop in the ovaries, they displace fluid from within the ovaries and it exudes from the ovaries into the peritoneal space when ovulation occurs.<sup>21</sup>

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11. Ovarian bursa (or tunica): Beneath the epithelial surface of the ovaries, where most tumors develop, there is a dense layer of bursa or tunica that would be very difficult for any particulate to penetrate.<sup>22</sup> Thus, if a study indicates that particulates were found deep within the ovarian tissue it should be considered suspect.

Use of talc on diaphragms, cervical caps, or a partner's condoms would bypass the labia minora and most of the vagina and deposit talc near the cervical os. However, the epidemiologic studies that have investigated these particular exposures have almost uniformly found no association, and more recent studies have dismissed a possible association based on those studies.

In summary, spermatozoa require self-contained propulsion (via their flagellae or tails) in order to ascend to the ampullary section of the oviducts. Even then, only a very tiny percentage of them arrive there. And spermatozoa are deposited near the opening to the cervix, and therefore escape the barriers created by the labia minora, collapsed vagina, and downward flow of vaginal and cervical mucus/exudate and menses. It is highly unlikely that inanimate particles deposited outside the vagina on the perineal skin could travel not only to the ampulla section of the oviducts, but completely through the oviducts and past the fimbriae. Even if they could, they would then have to travel across the peritoneal space between the fimbriae and the ovaries and attach to the surface of the ovaries (it being presumably nearly impossible for them to actually penetrate the ovaries) and escape phagocytosis. Thus, the hypothetical pre-condition to talc causing ovarian cancer – exposure of the ovaries to perineally-applied talc -- has not been established and appears to conflict with known anatomy and physiological processes in the female reproductive tract.

This subject was discussed at the two-day 1994 workshop sponsored jointly by FDA, CTFA, and IS RTP. (The workshop was attended by 110 individuals from government agencies, academia, industry, consulting, and the consumer sector.) In the consensus summary of the workshop it is stated that “[f]ollowing a presentation by Dr. Brown (University of Wisconsin), the discussion made it clear that available histologic and physiological studies provide no basis to conclude that talc can migrate to the ovaries from the perineal region.”<sup>23</sup>

The 2006 IARC review (published in 2010) that resulted in an evaluation of “possibly carcinogenic to humans” (with several dissents) (for “talc-based body powder,” not talc) found that the evidence for translocation was “weak.”<sup>24</sup> But the IARC reviewers did not consider the anatomical/physiological aspects of the translocation issue, and there were no gynecologists on the working group or participating as invited experts. In reality, as can be seen, the literature evidence for translocation from the perineum would be better characterized as non-existent, and taking into account anatomic and physiologic factors, the overall evidence would probably be best characterized as indicating that translocation of particulate matter from the perineum is very implausible.

### **Lack of Evidence of Granulomas, Inflammation, or Adhesions in the Reproductive Tract of Powder Users**

Talc is known to cause inflammation, foreign-body granulomas, and scarring or adhesions when introduced into the thoracic or peritoneal cavities, or into wounds or surgical

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incisions. The medical community generally stopped using talc-powdered surgical and examination gloves (as well as cornstarch-powdered gloves) for just this reason many years ago. Yet, despite talcum powder having been actively marketed and widely used by consumers for at least well over a century, there have never to our knowledge been published reports of inflammation, granulomas, or adhesions in the female reproductive system associated with perineal dusting with talcum powder (or cornstarch or other powder constituents). How can this be if talc is able to enter, and remain in, the reproductive system following use? The presence of talc particles in or on reproductive organs would cause inflammation, granulomas, and adhesions. Simply as a matter of common experience and societal knowledge, women would not use talcum powder as extensively as they have (in the range of forty percent in the United States) if they experienced inflammation, scarring, and granulomas. Medically, talcum powder usage has not been associated with tubal occlusion, pelvic inflammatory disease, or vaginitis. One would think that such an association would be easily discoverable in the pathology lab, by laparoscopy, or even visually during a gynecologic examination. And reports of talc found in or on ovarian tissue samples do not show typical signs of inflammation and granuloma formation. Because granulomas and adhesions form around particulate matter, and inflammation responses are detectable, the cause of any such abnormalities should be easy to diagnose if due to particulate matter. Note the findings of granulomas and “infections” in the Keskin et al. translocation study on rats.<sup>25</sup> Yet tissue samples purportedly showing particulates on or embedded in them have not been reported to show these typical signs, which seems to indicate that the presence of particulates occurred after the tissue was removed from the body and was due to contamination, either from ambient dust or surface dust.

### Lack of Consistency in the Risk Estimates in the Epidemiologic Studies

The draft SLR indicates at p.18 that the epidemiologic studies have shown “a fairly consistent association between perineal dusting with talc powders and ovarian cancers.” (Citation omitted). The body of epidemiology presents a semblance of consistently positive (though mainly statistically non-significant) weak associations; however, it should be noted that, as discussed above, many of the studies, particularly many showing a statistically positive association, did not specifically study talc (as opposed to other types of powders or sprays) as an exposure; and most of the studies, when examined from the viewpoint of types of exposure or frequency/duration categories, show associations that are either not statistically significant or negative (see Table 9 of the draft SLR).

In a significant number of studies (13), exposure via sanitary pads or underwear is broken out separately – and such “indirect” exposure should result in just as much direct exposure to the perineum as “direct” dusting of the perineum. Table 4 lists RRs/ORs from all of the studies that broke out exposure via sanitary pads and/or underwear separately.

**Table 4: Exposure via sanitary pads or underwear**

Study (alphabetical)	RR/OR
Chang & Risch 1997	1.26 (0.81-0.96)
Cook 1997	0.9 (0.5-1.5)
Cramer 1982	1.52 (0.98-2.47)



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Cramer 1999	san. pd. 1.45 (0.68-3.09) undwr. 1.21 (0.40-2.8)
Gertig 2000	0.89 (0.61-1.28)
Harlow 1992	1.1 (0.4-2.8)
Karageorgi 2010	0.98 (0.75-1.27)
Ness 2000	san. pd. 1.6 (1.1-2.3) undwr. 1.7 (1.2-2.4)
Rosenblatt 1992	4.8 (1.3-17.8)
Rosenblatt 2011	0.82 (0.58-1.16)
Whittemore 1988	0.62 (0.21-1.80)
Wong 1999	0.9 (0.4-2.0)
Wu 2009	san. pd. 1.61 (0.93-2.78) undwr. 1.71 (0.99-2.97)

While the number of subjects exposed via these modes was relatively small in many of the above studies (as indicated by the confidence intervals), it appears that a pooling or meta-analysis would yield a considerably lower RR/OR than the 1.3 or 1.4 generally attributed to “perineal” exposure as a whole.

As has been frequently noted in the studies themselves, the overall body of epidemiology studies is very inconsistent with regard to dose-response, with many showing a lack of a consistent positive dose-response, and some even indicating an inverse dose-response. This is inconsistent with basic principles of toxicology.

It should also be noted that a number of all the studies were “ever/never” studies, which is a crude study design, especially since it might be more susceptible to recall bias (discussed below).

### Basis for Recall Bias

It is generally recognized that case-control epidemiologic studies are particularly susceptible to recall bias by cases. This is because cases (*i.e.*, women diagnosed with cancer) have a tendency to search out, or recall more frequently, exposures that they believe, or that others believe, might have caused their cancer. Cases might conduct library or Internet searches or discuss their disease with friends and support groups. *Zota et al.*<sup>26</sup> recently investigated possible recall bias among women with breast cancer in a case-control study examining possible association with home cleaning, air-freshener, and insecticide products. They found that RRs were weakly elevated (about 2.0) for association with cleaning and air-freshener products (and very weakly for some insecticide products) among women who believed that chemicals and air pollution contribute “a lot” to breast cancer as compared with cases who did not have such a belief. This study appears uniquely analogous to the case-control studies here because it involved a female reproductive system cancer and similarly weak RRs.

The IARC working group recognized the susceptibility of case-control studies to recall bias, but tended to discount it on the basis that the largest flurry of publicity concerning cancer and talc-based body powders occurred in the mid-1970’s, and possibly very close to early 2006 (when the working group met), and in between those times “it was the opinion of the Working Group that there had not been widespread public concern about this issue ....”<sup>27</sup> This seems like

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odd reasoning because the study cohorts ages spanned the 1970s and because, while the working group or IARC staff apparently did not conduct research on the subject, there appears to have been, in fact, wide reporting of both the asbestos-in-powders cancer issue in the 1970s and subsequent case-control studies through the 1980s and 1990s. A search of the ProQuest database of newspaper and periodicals articles from 1976 to very recently turned up hundreds of stories of this sort.<sup>28</sup> Some examples from major U.S. newspapers (and there are many more from smaller newspapers and other English-speaking countries such as England, Canada, and Australia where epidemiologic studies were conducted) include the following, copies of which are attached:

“Asbestos Fibers Found in Baby Powder,” The Washington Post, Mar. 8, 1976, p. A1.

“Study finds asbestos in 9 body powders,” The Boston Globe, Mar. 8, 1976, p. 2.

“10 of 19 talc powders found to have asbestos,” Baltimore Sun, Mar. 9, 1976, p. A3.

“Asbestos Found in Baby Powders,” Los Angeles Times, Mar. 8, 1976, p. A7.

“Asbestos Found in Ten Powders,” New York Times, Mar. 10, 1976, p. 43.

“Study links talcum powder use to ovarian cancer,” Associated Press - Baltimore Sun, Aug. 6, 1982, p. A3. (Article on Cramer *et al.* 1982 study.) (Note that AP stories are distributed to thousands of daily newspapers and other media outlets both nationally and internationally. Just in the U.S., about 1,400 daily papers are AP subscribers.)

“Hospital Study Ties Talc Use to Ovarian Cancer,” Associated Press - The Hartford Courant, Aug. 6, 1982, p. A3. (Article on Cramer *et al.* 1982 study.)

CNN transcript for story regarding release of Cancer Prevention Coalition and Nader group’s “dirty dozen” list, which included talcum powder, Sept. 21, 1995 (10 pm news).

“The Perils of Powders,” Time, Inc. Health, Sept. 1996, p. 17. (ProQuest abstract of article on Cook *et al.* 1997 study (advance release 1996).)

“Genital powders linked to cancer use tied to ovarian cancer, reports study by Hutchinson Center,” Associated Press – Seattle Post-Intelligencer, Mar. 5, 1997, p. B1 (ProQuest abstract of article on Cook *et al.* 1997 study.)

“Study links ovarian cancer, use of feminine products ...,” Orlando Sentinel, Mar. 5, 1997, p. A15. (ProQuest abstract of article on Cook *et al.* 1997 study.)

“Ovarian cancer risk linked to powder, sprays,” Associated Press - Denver Post, Mar. 5, 1997, p. A7. (ProQuest abstract of article on Cook *et al.* 1997 study.)

Perhaps more important than the above hard-copy publications for relevance to recall bias is the development, since roughly the mid- to late-1990s, of an individual’s ability to easily search the Internet for pertinent materials, whether health literature, news articles, or non-expert advice/advertisements. Internet use began to explode in the mid-1990s along with new search



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engine capabilities. PubMed became widely available in about 1999-2000,<sup>29</sup> allowing women to access all the epidemiologic studies cited herein. For many years the Internet has provided access to a multitude of articles and advertisements with advice to use “talc-free” body powders because talc is linked to cancer and is similar to asbestos. For example, a current Internet search on Google for “ovarian cancer baby powder” will turn up about 236,000 (not a typo) results. Regardless of the content of the postings, an ovarian cancer patient picked for a case-control study could be sensitized by such materials to the talc-ovarian cancer hypothesis and be more primed to recall use of any sort of powder applied to the perineum.

### Conclusions

- Talcum powder and cosmetics containing talc have been used by consumers for well over a century with no reports of adverse effects or discomfort unless used inappropriately or accidentally inhaled in large quantities.
- There is convincing evidence that talc is not carcinogenic. The notion that talc is similar to asbestos has been shown to be unsupported. Talc is non-genotoxic and non-tumorigenic *in vitro* and in animal experiments, and has been proven non-carcinogenic through its widespread use in medical pleurodesis and pharmaceuticals, and occupationally by millers. A number of experiments have even indicated that talc has cancer-inhibiting properties (anti-angiogenic and promoting apoptosis).
- The numerous case-control studies -- allegedly of exposure to “talc,” but often actually based on exposure to various powders or sprays of unknown composition – and ovarian cancer are far too problematic to raise significant doubts regarding talc safety. Serious problems with the ovarian epidemiologic studies include the following (not necessarily in order of importance):
  1. There is no evidence that powder applied externally to the perineum is able to translocate to the ovaries. Basic anatomic and physiologic knowledge concerning the female reproductive system indicates strongly that it is not possible for talc ordinarily to gain entrance to the system, and if it does, to move through the vagina, cervical canal, uterus, and oviducts, and across the peritoneal space from the oviducts to the ovaries and escape phagocytosis. Analyses of the results of studies asking about use of talc on diaphragms, cervical caps, or condoms, which would deposit talc farther inside the reproductive tract, have not shown a positive association. This knowledge is augmented strongly by very long practical consumer and gynecologic experience in which perineal powders that should cause inflammation, granulomas, scarring, and adhesions if particles entered the reproductive system have not been reported to be associated with such lesions. Because talc (as well as some other particulates resembling talc, such as zeolite) is ubiquitous in dust due to its many common uses, and because particles supposedly talc found on ovarian tissue specimens do not show surrounding typical signs of inflammation or granulomatous formation, it is likely that any such findings are due to ordinary dust contamination after surgical removal.

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2. All of the epidemiologic study cohorts have age ranges overlapping the period prior to 1976 when asbestos was supposedly detected in significant quantities in some brands of body powders.
3. Many of the epidemiologic studies were studies of exposure to various types of powders or sprays in addition to talcum powder. Most other studies do not provide the actual question(s) asked of subjects regarding exposures. Moreover, it is not clear that many consumers (or study subjects) recognize talcum powder as a type of powder distinct from talc-free powders.
4. As a body, the majority of studies show very weak RRs or ORs that are not statistically significant. In particular, studies reporting risks from exposure via sanitary pads or underwear (in addition to those reporting on use of talc on diaphragms and condoms) appear to be either negative or extremely weak.
5. The majority of studies do not show a positive biological gradient (increasing risk with increasing exposure), which is one of the hallmarks of toxicity.
6. Case-control studies are recognized as susceptible to recall bias, and it can be shown that the talc-cancer hypothesis has received widespread publicity since at least 1976 (when asbestos contamination was reported in some brands of body powders), and particularly since Internet access by the general public became more available and popular beginning towards the end of the twentieth century.
7. The only prospective cohort study was essentially non-positive.

We look forward to Expert Panel review and discussion of this matter.

Respectfully,

/s/

William G. Kelly, Jr.  
Center for Regulatory Effectiveness

Attachments (news articles and abstracts)

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- <sup>6</sup> Jones RE, *Human Reproductive Biology*, 2d ed., Academic Press 1997, pp. 165-66.
- <sup>7</sup> Mescher, *supra*, p. 393.
- <sup>8</sup> Graphic based on graphics in Mescher, *supra*, p. 390.
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- <sup>11</sup> See Jones RE, *supra*, p. 43.
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- <sup>16</sup> U.S. Dept. of Health and Human Serv., Nat'l Women's Health Inform. Ctr., Office of Women's Health. 2011. *Frequently Asked Questions* ("Most doctors say that it is best to let your vagina clean itself. The vagina cleans itself naturally by producing mucous.") (available at <http://www.womenshealth.gov/publications/our-publications/fact-sheet/douching.cfm#f> ).
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- <sup>18</sup> See Jones RE, *supra*, pp. 41, 165-66.
- <sup>19</sup> Page EW *et al.*, *Human Reproduction*, 2d ed., W. B. Saunders Co. 1976, p. 37.
- <sup>20</sup> Mescher, *supra*, p. 395. See also Page EW *et al.*, *supra*, p. 37.
- <sup>21</sup> Mescher, *supra*, p. 393.
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<sup>24</sup> IARC monograph 93 (2010) at 411.

<sup>25</sup> Keskin N *et al.* 2009. Does long-term talc exposure have a carcinogenic effect on the female genital system of rats? An experimental pilot study. *Arch Gynecol Obstet* 280(6):925-31.

<sup>26</sup> Zota AR *et al.* 2010. Self-reported chemicals exposure, beliefs about disease causation and risk of breast cancer in the Cape Cod Breast Cancer and Environment Study: a case control study. *Environ Health* 9:40.

<sup>27</sup> IARC monograph 93, *supra*, at 409.

<sup>28</sup> Personal search done by W. Kelly (signatory of these comments) at Library of Congress. The ProQuest database covers over 2500 newspapers and periodicals and other media; however, full text copies of articles are available for only about half the entries, with abstracts provided for the other entries. The ProQuest database tends to focus on major media. A more comprehensive search, and one that returns full-text articles, could probably be conducted through the Readers Guide to Periodical Literature with copies of entries retrieved from microfilm. Such a search would be somewhat time-consuming. The ProQuest search reflected in these comments was conducted in less than a day.

<sup>29</sup> See "PubMed Celebrates its 10<sup>th</sup> Anniversary!" National Library of Medicine technical bulletin posted Oct. 5, 2006. Available at [http://www.nlm.nih.gov/pubs/techbull/so06/so06\\_pm\\_10.html](http://www.nlm.nih.gov/pubs/techbull/so06/so06_pm_10.html).



## Asbestos Fibers Found in Baby Powder: Asbestos Fibers Found in Powders

By Marian Burros Washington Post Staff Writer

*The Washington Post* (1974-Current file); Mar 8, 1976;

ProQuest Historical Newspapers: The Washington Post (1877-1995)

pg. A1

# Asbestos Fibers Found in Baby Powder

By Marian Burros

Washington Post Staff Writer

Asbestos fibers, which are found in thousands of products from food to building insulation, have been discovered in nine of 19 baby powders studied by researchers at Mt. Sinai Hospital in New York.

Asbestos can cause mesothelioma, a rare form of chest and abdominal cancer, and asbestosis, scarring of lung tissue. In 1972 Dr. William J. Nicholson of Mt. Si-

nai reported that these diseases caused nearly 40 percent of the deaths of New York-New Jersey asbestos workers.

Dr. Irving J. Selikoff of Mt. Sinai, a leading expert on occupational disease, said, "We do not know a safe threshold level for a carcinogen like asbestos." Once asbestos fibers enter the body, he said, they stay there.

Researchers at Mt. Sinai's Department of Environmen-

tal Medicine tested one sample each of 19 baby and baby powders. Arthur M. Langer, head of the physical sciences section of the department, said nine samples contained asbestos fibers in quantities ranging from "2 to 20 per cent."

The powders with the greatest concentration of asbestos fibers, ranging from 8 to 20 per cent, were ZBT Baby Powder with baby oil, Cashmere Bouquet Body

Talc, Coty Airspun Face Powder and Rosemary Talc.

Bauer & Black Baby Talc, which is no longer on the market, had a 15 per cent concentration of asbestos fibers, the researchers found.

Smaller amounts of asbestos fibers—under 5 per cent—were found in Faberge Brut Talc, Yardley Invisible Talc, Yardley Black Label Body Powder, Mennen Shave Talc and English Leather After Shave Talc.

See **POWDER, A7, Col. 1**

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# Asbestos Fibers

## Found in Powders

Officials of Colgate Palmolive, which makes Cashmere Bouquet, Sterling Drugs, Inc., manufacturer of ZBT Baby Powder and of Coty said they are certain their products are safe. They said no asbestos had been found in their testing.

The manufacturer of Rosemary Talc could not be reached for comment.

The other powders studied were Ammen's Medicated Powder; Avon Bird of Paradise Beauty Dust; Diaperene Medicated Body Powder; Johnson's Baby Powders, one made in England and one in the United States; Johnson's Medicated Powder; Mennen Bath Talc; Yardley After Shave Powder and Yardley Original Body Powder. None of them contained asbestos. One, Diaperene, contained no talc. It is made of cornstarch.

The Food and Drug Administration said in 1972 it would propose regulations to govern the use of asbestos-contaminated talc in cosmetics. The director of FDA's division of cosmetics technology, Heinz J. Eirmann, said recently the agency had not issued regulations because it had not found a "fast method" for determining the presence of asbestos at low levels. The sophisticated method used at Mt. Sinai, electron microscopy, he said, was too time consuming and expensive.

The Mt. Sinai researchers, who have conducted the study under a grant from the National Institute of Environmental Health Services since 1973, also investigated the powders for the presence of other metallic elements, including nickel.

With the exception of Rosemary Talc and Diaperene which contained no nickel, 16 of the powders contained from 4 to 710 parts per million (ppm) of nickel. A sample of Johnson's Baby Powder contained 2,200 ppm.

Surprised at what they regarded as a high nickel con-

ten of the powders, the researchers purchased seven more samples. Five of them had 1,800 ppm or more of nickel; two had fewer than 710 ppm. Langer said researchers "don't know if the nickel is hazardous at high levels."

Dr. F. William Sunderman, Jr., head of the department of laboratory medicine at the University of Connecticut and an expert on nickel, said: "We're trying to find out which nickel compounds do cause cancer and which don't. Certain nickel compounds are carcinogenic when inhaled; others are not."

Johnson & Johnson's associate director for public affairs, Robert Kniffin, said the nickel in the talc is "harmless" because "it is biologically inert" and won't react with body tissues.

A study revealed last September by Dr. J. C. Wagner of the Pneumoconiosis Research Unit at Penarth, Wales, raised the question about the safety of talc itself, the major ingredient in powders. Wagner found that asbestos-free talc caused fibrosis, lung scarring in the test animals "at the same rate as asbestos."

Epidemiological studies have shown that talc workers develop talcosis, another form of lung scarring, from exposure to large amounts of the mineral.

According to Selikoff, the amount of talc that must be inhaled to cause tissue scarring or cancer in humans is not known.

# Asbestos Found In Ten Powders

Ten out of 19 body and baby powders tested at Mount Sinai Hospital here were contaminated with asbestos fibers capable of causing a rare form of chest and abdominal cancer, researchers have reported.

Dr. Arthur Rohl, who conducted the tests with Dr. Arthur Langer, said of the findings: "There is no firm evidence on low-level or intermittent exposure, such as from using talcum powder. We don't know for sure what the danger level is."

The researchers said the contamination usually was found in the talc used in the powders. Asbestos fibers can cause mesothelioma, a chest and abdominal cancer, and can also result in the scarring of lung tissue and gastro-intestinal difficulties, Dr. Rohl said.

The researchers said that 10 of the 19 American samples contained from 2 percent to 20 percent asbestos fibers with the highest concentration in ZBT Baby Powder with Baby Oil. Cashmere Bouquet Body Talc, Coty Airspun Face Powder and Rosemary Talc range from 8 percent to 20 percent asbestos fibers.

Bauer & Black Baby Talc, which is no longer on the market, had a 15 percent concentration. Other powders containing less than 5 percent asbestos were Fabergé Brut Talc, Yardley Invisible Talc, Yardley Black Label Baby Powder, Mennen Shave Talc and English Leather After Shave Talc.

The manufacturers that could be reached for comment said that they were convinced that their products were safe and that their own tests had shown no asbestos. Only the manufacturer of Rosemary could not be reached.

The products that the researchers found uncontaminated with asbestos fibers were Ammen's Medicated Powder, Avon Bird of Paradise Beauty Dust, Diaperene Medicated Body Powder; two Johnson's Baby Powders (one made here and one in Britain), Johnson's Medicated Powder, Mennen Bath Talc, Yardley After Shave Powder and Yardley Original Body Powder.

The tests at Mt. Sinai, which Federal health officials described as the country's leading research facility looking into the possible dangers of asbestos, used an electron microscope, which Heinz J. Elrmann, director of cosmetics technology in the Food and Drug Administration, said was too expensive and time-consuming for his agency to use.

The experiments at Mt. Sinai, which Dr. Rohl described as the only significant inquiry on the subject ever held, were financed by a grant from the National Institute of Environmental Health Services and were begun in 1973.



## Study finds asbestos in 9 body Powders

Burtons, Marian

*Boston Globe (1960-1981); Mar 8, 1976; ProQuest Historical Newspapers: Boston Globe (1872-1981)*  
pg. 2

# Study finds asbestos in 9 body powders

By Marian Burros  
Washington Post

WASHINGTON—Asbestos fibers, found in thousands of products from food to building insulation, have been discovered in nine of 19 body and baby powders studied by researchers at Mt. Sinai Hospital in New York.

Asbestos can cause mesothelioma, a rare form of chest and abdominal cancer, and asbestosis, scarring of lung tissue. In 1972 Dr. William J. Nicholson of Mt. Sinai reported that these diseases caused nearly 40 percent of the deaths of New York and New Jersey asbestos workers.

Dr. Irving J. Selikoff of Mt. Sinai, a specialist on occupational disease, said "We do not know a safe threshold level for a carcinogen like asbestos." Once asbestos fibers enter the body, he said, they stay there.

Researchers at Mt. Sinai's Department of Environmental Medicine tested one sample each of 19 body and baby powders. Arthur M. Langer, head of the physical sciences section of the department, said nine samples contained asbestos fibers in quantities ranging from 2 to 20 percent.

The powders with the greatest concentration of asbestos fibers, ranging from 8 to 20 percent, were ZBT Baby Powder with baby oil, Cashmere Bouquet Body Talc, Coty Airspun Face Powder and Rosemary Talc.

Bauer & Black Baby Talc, no longer on the market, had a 15 percent concentration of asbestos fibers, the researchers found.

Smaller amounts of asbestos fibers — under 5 percent — were found in Faberge Brut Talc, Yardley Invisible

The powders with the greatest concentration of asbestos fibers were ZBT Baby Powder, Cash-

mere Bouquet Body Talc, Coty Airspun Face Powder and Rosemary Talc.

Talc, Yardley Black Label Body Powder, Mennen Shave Talc and English Leather After Shave Talc.

Officials at Colgate Palmolive, which makes Cashmere Bouquet, and at Sterling Drugs, Inc., manufacturer of ZBT Baby Powder and of Coty,

said they are certain their products are safe. They said no asbestos had been found in their testing.

The manufacturer of Rosemary Talc could not be reached for comment.

The other powders studied were Ammen's Medicated Powder, Avon Bird of Paradise Beauty Dust, Diaperene Medicated Body Powder, Johnson's Baby Powders — one made in England and one in the United States — Johnson's Medicated Powder, Mennen Bath Talc, Yardley Original Shave Powder and Yardley Original Body Powder. None of them contained asbestos. Diaperene contained no talc; it is made of cornstarch.

The Food and Drug Administration said in 1972 it could propose regulations to cover the use of asbestos-contaminated talc in cosmetics.

The director of FDA's division of cosmetics technology, Heinz J. Elmann, recently said the agency had not issued regulations because it had not found a fast method for determining the presence of asbestos at low levels. The sophisticated method used at Mt. Sinai, electron microscopy, is too time-consuming and expensive, he said.

The Mt. Sinai researchers, who have conducted the study under a grant from the National Institute of Environmental Health Services since 1973, also investigated the powders for the presence of other metallic elements, including nickel.

With the exception of Rosemary Talc and Diaperene, which contained no nickel, 16 of the powders contained from 4 to 710 parts per million of nickel. A sample of Johnson's Baby Powder contained 2200 ppm.

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Asbestos Found in Baby Powders: Incomplete Source  
BURROS, MARIAN  
*Los Angeles Times* (1923-Current File); Mar 8, 1976;  
ProQuest Historical Newspapers: Los Angeles Times (1881-1988)  
pg. A7

# Asbestos Found in Baby Powders

## Some Body Talcs Also Contained Carcinogen

**BY MARIAN BURROS**

**The Washington Post**

WASHINGTON—Asbestos fibers, found in thousands of products from food to building insulation, have been discovered in nine of 19 body and baby powders studied by researchers at Mt. Sinai Hospital in New York.

Asbestos can cause mesothelioma, a rare form of chest and abdominal cancer, and asbestosis, scarring of lung tissue. In 1972 Dr. William J. Nicholson of Mt. Sinai reported that these diseases caused nearly 40% of the deaths of New York-New Jersey asbestos workers.

Dr. Irving J. Selikoff of Mt. Sinai, a leading expert on occupational disease, said, "We do not know a safe threshold level for a carcinogen like asbestos." Once asbestos fibers enter the body, he said, they stay there.

Researchers at Mt. Sinai tested one sample each of 19 body and baby powders. Arthur M. Langer, head of the hospital's physical sciences section, said nine samples contained as-

**Please Turn to Page 13, Col. 1**



# Asbestos Fibers Found in Some Baby, Body Powders

**Continued from First Page**

bestos fibers in quantities ranging from 2% to 20%.

The powders with the greatest concentration of asbestos fibers, ranging from 8% to 20%, were ZBT Baby Powder with baby oil, Cashmere Bouquet Body Talc, Coty Airspun Face Powder and Rosemary Talc.

Bauer & Black Baby Talc, no longer on the market, had a 15% concentration of asbestos fibers, the researchers found.

Smaller amounts of asbestos fibers—less than 5%—were found in Faberge Brut Talc, Yardley Invisible Talc, Yardley Black Label Body Powder, Mennen Shave Talc and English Leather After Shave Talc.

Spokesmen at Colgate Palmolive, which makes Cashmere Bouquet, and Sterling Drugs, Inc., manufacturer of ZBT Baby Powder and of Coty, said they were certain their products were safe. They said no asbestos had been found in their testing.

The manufacturer of Rosemary Talc could not be reached for comment.

The other powders studied were Ammen's Medicated Powder, Avon Bird of Paradise Beauty Dust, Diaperene Medicated Body Powder, Johnson's Baby Powders (one made in England and one in the United States), Johnson's Medicated Powder, Mennen Bath Talc, Yardley After Shave Powder and Yardley Original

Body Powder. None of them contained asbestos. One, Diaperene, contained no talc. It is made of cornstarch.

The Food and Drug Administration said in 1972 it would propose regulations to cover the use of asbestos-contaminated talc in cosmetics.

The director of FDA's division of cosmetics technology, Heinz J. Eirmann, said recently that the agency had not issued regulations because it had not found a "fast method" for determining the presence of asbestos at low levels. The sophisticated method used at Mt. Sinai, electron microscopy, is too time-consuming and expensive, he said.

The Mt. Sinai researchers investigated the powders for the presence of other metallic elements, including nickel, also.

With the exception of Rosemary Talc and Diaperene, which contained no nickel, 16 of the powders contained from 4 to 710 parts per million (ppm) of nickel. A sample of Johnson's Baby Powder contained 2,200 ppm.

Langer, of Mt. Sinai, said researchers "don't know if the nickel is hazardous at high levels."

Johnson & Johnson's associate director for public affairs, Robert Kniffin, said the nickel in the talc was "harmless," because "it is biologically inert" and would not react with body tissues.

# 10 of 19 talc powders found to have asbestos

New York (AP)—Ten out of 19 body and baby powders tested at Mount Sinai Hospital here were contaminated with asbestos fibers capable of causing a rare form of chest and abdominal cancer, researchers said yesterday.

Dr. Arthur Rohl, who conducted the tests with Dr. Arthur Langer, said there has been no investigation of the dangers from asbestos in such powders.

"There should be some sort of quality control instituted either by the industry or by congressional legislation," he said in an interview.

The researchers said the contamination usually was found in the talc used in the powders.

Asbestos fibers can cause mesothelioma, a chest and abdominal cancer, and can also result in the scarring of lung tissue and gastrointestinal difficulties, Dr. Rohl said.

The researchers said:

- The highest concentration was in ZBT Baby Powder with Baby Oil; Cashmere Bouquet Body Talc, Coty Airspun Face Powder and Rosemary Talc. These were in the 8 per cent to 20 per cent bracket.

- Rosemary also contained 30 per cent quartz.

- Bauer & Black Baby Talc, which is no longer on the market, had a 15 per cent concentration.

- Other powders containing less than 5 per cent asbestos were Faberge Brut Talc, Yardley Invisible Talc, Yardley Black Label Body Powder, Mennen Shave Talc and English Leather After Shave Talc.

The manufacturers of Rosemary could not be reached for comment, but the others said they were convinced their products were safe and said their own tests had shown no asbestos.

The baby and body powder tests were undertaken as part

of a study of the dangers involved in occupational exposure to asbestos, Dr. Rohl said.

"There is no firm evidence on low level or intermittent exposure such as from using talcum powder," he said. "We don't know for sure what the danger level is."

The tests at Mount Sinai used electron microscopy. Heinz J. Eirmann, director of cosmetics technology in the federal Food and Drug Administration, said it was too expensive and time consuming for the agency to use. There is no "fast control" method, he said.



## Study links talcum powder use to ovarian cancer

*The Sun* (1837-1986); Aug 6, 1982; ProQuest Historical Newspapers: Baltimore Sun, The (1837-1986) pg. A3

# Study links talcum powder use to ovarian cancer

Boston (AP)—Talcum powder has been linked to ovarian cancer in a study that found women who dusted their genitals and sanitary napkins with talc were three times as likely to develop tumors.

The study, done by Brigham and Women's Hospital here, compared the hygiene habits of 215 Boston-area women who had ovarian cancer to a control group of 215 healthy women.

It found that 32 women with the cancer used talcum powder on their genitals and sanitary napkins. Only 13 of the women in the non-cancer group

used the talc in that way.

Other factors considered in the study raise the risk of ovarian cancer to 3.28 times greater for women who use talc than for women who don't, the report said.

The survey found that women whose genitals had some exposure to talcum powder had almost a two-fold cancer risk.

The study was the first of its kind to link talc use to ovarian cancer, the fifth leading cause of cancer deaths among women. An estimated 18,000 cases are diagnosed a year, and

12,000 women die from the disease annually.

Dr. Daniel W. Cramer, the obstetrician and gynecologist who wrote of the findings in the July edition of the journal *Cancer*, said further studies are needed before doctors could recommend that women should not use talc.

"We would like to see other researchers find the same thing and we would like to see animal experiments," he said.

But he said he now advises patients to use other products, such as

cornstarch-based powders or creams.

"I do make a comment that maybe it isn't such a good idea" to use talc, he said. "I think the evidence is rather tenuous in relationship to talc and ovarian cancer, but the use of talc on the genitals has rather marginal benefits, so I caution my patients."

He said most of the body powders on the market are talc-based, and the ingredients usually are marked.

Dr. Cramer said talc is a magnesium silicate similar to asbestos, which has been linked to lung cancer.

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Hospital Study Ties Talc Use to Ovarian Cancer  
 Bayles, Fred  
*The Hartford Courant* (1923-1986); Aug. 6, 1982  
 ProQuest Historical Newspapers: Hartford Courant (1764-1986)  
 pg. A3

# Hospital Study Ties Talc Use to Ovarian Cancer

By FRED BAYLES  
*Associated Press*

BOSTON — Talcum powder, long used to smooth babies' bottoms, has been linked to ovarian cancer in a study that found women who dusted their genitals and sanitary napkins with talc were three times as likely to develop tumors.

The study, done by Brigham and Women's Hospital here, compared the hygiene habits of 215 Boston-area women who had ovarian cancer to a control group of 215 healthy women.

It found that 32 women with the cancer had used talcum powder on their genitals and sanitary napkins. Only 13 of the women in the non-cancer group had used the talc in that way.

Other factors considered in the study raise the risk of ovarian cancer to 3.28 times greater for women who use talc than for women who do not, the report said.

The survey found that women whose genitals had some exposure to talcum powder had about a two-fold cancer risk.

The study was the first of its kind to link talc use to ovarian cancer, the fifth-leading cause of cancer deaths among women. An estimated 18,000 cases are diagnosed a year, and 12,000 women die from the disease each year.

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He said most of the body powders on the market are talc-based, and the ingredients usually are marked.

Cramer said talc is a magnesium silicate similar to asbestos, which has been linked to lung cancer. He also said some talcum powders have been found to be contaminated with asbestos.

He said researchers have found that magnesium silicate particles have been linked to cancers in tissues that line the body organs, such as the ovaries and the lungs.

James Murray, a spokesman for Johnson & Johnson, the nation's largest producer of talcum powder, said the company would have to read the study before making any comment. He said his company's product has no asbestos contamination.

Cramer said there is no indication from the study that talc presents a risk to infants.

"Infants have a shorter period of exposure time and it doesn't seem that the female genital tract in an infant is open to exposure," he said.



SEP 25 '95 10:24AM CPI-PRE CLINICAL  
2ND STORY of Level 1 printed in FULL format.

FULL

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SECTION: News; Domestic

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HEADLINE: Consumer Activists Group Release List of 'Dirty' Dozen

BYLINE: EUGENIA HALSEY

HIGHLIGHT: A consumer activists group released a list of 12 common household products that it says may contribute to cancer. A group representing some of the manufacturers calls the announcement a publicity stunt.

BODY:

BOBBIE BATTISTA, Anchor: Well, consumer advocate Ralph Nader is known for taking on tough opponents and today, he's at it again.

LINDEN SOLES, Anchor: That's right. Now he accusing industry titans of selling products that could heighten the risk of cancer, even though the government says the products are safe. Here's CNN's Eugenia Halsey.

EUGENIA HALSEY, Correspondent: The list, called the 'dirty dozen' includes some of the most popular household cleansers, cosmetics and food, everything from baby powder to beef hot dogs and toothpaste. It's contained in a new book who's authors say consumers have no way of knowing whether the products may increase the risk of cancer and other diseases because there are no warning labels.

1st CONSUMER ACTIVIST: We label for cholesterol but not for carcinogens.

EUGENIA HALSEY: But an industry group representing the makers of ten of the 12 products called the list a publicity stunt to promote the book and said all of the products are perfectly safe.

JEFF NEDELMAN, Grocery Manufacturers of Amer.: These health and beauty care products- the household cleaners are extensively tested. The federal standards are very, very stringent.

EUGENIA HALSEY: The Food and Drug Administration and the Environmental Protection Agency also insisted the products are safe, saying the toxic substances some of them contain are too tiny to harm anyone. But consumer activist Ralph Nader says the incidence of cancer in the United States is increased at least 45 percent since 1950 and that the cumulative effects of these industrial chemicals outside, in the workplace and at home may be contributing to the rise in disease.

SEP 25 '95 10:25AM CPI-PRE CLINICAL 114666  
NEWS, September 21, 1995

P.7/7

RALPH NADER, Consumer Activist: The American people need to know that the- the pool of carcinogens in a complex industrial society is growing.

EUGENIA HALSEY: Nader says there are safer alternatives in the supermarket, including some made by the same manufacturer. For instance, he says you can buy Johnson's Baby Powder with Corn Starch the may be safer than Johnson's Baby Powder with Talc. Johnson and Johnson issued a statement saying its talc is free of impurities and is not carcinogenic. Nader's group claims it is not trying to scare anyone, but simply giving people information they can use. Eugenia Halsey, CNN, Washington.

The preceding text has been professionally transcribed. However, although the text has been checked against an audio track, in order to meet rigid distribution and transmission deadlines, it may not have been proofread against tape.

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**Authors:** Carey, Benedict  
Mason, Michael

**Source:** Health (Time Inc. Health); Sep96, Vol. 10 Issue 5, p17, 1/6p

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**Subject Terms:** \*OVARIES -- Diseases  
\*HYGIENE products  
RISK factors

**Abstract:** Cites research at the University of Washington on the possible role of feminine hygiene powders in causing ovarian cancer. Increased risk of ovarian cancer for women who dust themselves with talcum, baby or scented bath powder in their genital areas.

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## THE PERILS OF POWDERS

Seattle--Despite pastel packaging and floral fragrances, feminine hygiene powders and powder-based sprays often contain harsh ingredients--so harsh that some researchers fear they may contribute to ovarian cancer. Researchers at the University of Washington recently compared 322 women with ovarian cancer to 426 women without. Those with cancer, the scientists discovered, were 50 percent more likely to have used a powder-based product in their genital area.

Several previous studies have hinted at an increased risk of ovarian cancer for women who dust themselves with talcum, baby, or scented bath powder. Researchers think tiny particles may travel through the reproductive tract and lodge in ovarian tissue. So what's the safest way to feel clean all over? The expert's advice: Take a bath.

~~~~~  
By Benedict Carey and Michael Mason

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### GENITAL POWDERS LINKED TO CANCER USE TIED TO OVARIAN CANCER, REPORTS STUDY BY HUTCHINSON CENTER: [FINAL EDITION]

PEGGY ANDERSEN THE ASSOCIATED PRESS. *Seattle Post - Intelligencer* [Seattle, Wash] 05 Mar 1997: B.1.

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#### Abstract (summary) [Translate \[unavailable for this document\]](#)

Women may increase their risk of ovarian cancer with the use of powder, especially in genital sprays and after bathing, suggests a study by the Fred Hutchinson Cancer Research Center and the University of Washington .

Researchers said the findings were clouded by the lack of specific brand information, details about individual powder use and by the unavailability of women eligible for the study who died before they could participate or were too ill to take part.

But the researchers said that since use of powder in the genital area is so prevalent among women - ranging from 28 percent to 51 percent in this and other studies - "even the modest elevation in ovarian cancer risk . . . suggested by most of the epidemiological studies could have a notable impact on the incidence of ovarian cancer in the United States."

#### Indexing (details) [Cite](#)

|                         |                                                                                                                                         |
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# STUDY LINKS OVARIAN CANCER, USE OF FEMININE PRODUCTS WHAT IS NOT CLEAR, HOWEVER, IS HOW THE APPLICATION OF THESE ITEMS MIGHT TRIGGER THE DEVELOPMENT OF THE DISEASE.: [METRO EDITION]

Seattle Times. *Orlando Sentinel* [Orlando, Fla] 05 Mar 1997: A15.

Hide highlighting

## Abstract (summary) Translate [unavailable for this document]

The study found there was a 50 percent higher risk for developing ovarian cancer among women who used a genital deodorant spray or powdered genital areas after bathing, said Linda Cook, an epidemiologist at Fred Hutchinson who was the study's lead author. Among the women with ovarian cancer, 30 percent had a history of dusting genital areas with talcum, bath or body powder after bathing. That compares with 21 percent of the control women who used such powders. And 13 percent of women with ovarian cancer used genital deodorant sprays, compared with 9 percent in the control group, Cook said.

## Full Text Translate [unavailable for this document]

Women diagnosed with ovarian cancer had a higher likelihood of having used genital powders and sprays than women who don't have the disease, according to a study conducted by the Fred Hutchinson Cancer Research Center.

The study, which began in 1986, compared 735 women in the Seattle area. The group, ages 20 to 79, included 313 women diagnosed with ovarian cancer and 422 randomly selected women with no history of ovarian cancer.

The study has been published in the American Journal of Epidemiology. The women were asked questions about their use of genital deodorant sprays, storing diaphragms in powder, dusting genital areas with powders after bathing and sprinkling powder on sanitary napkins.

The study found there was a 50 percent higher risk for developing ovarian cancer among women who used a genital deodorant spray or powdered genital areas after bathing, said Linda Cook, an epidemiologist at Fred Hutchinson who was the study's lead author. Among the women with ovarian cancer, 30 percent had a history of dusting genital areas with talcum, bath or body powder after bathing. That compares with 21 percent of the control women who used such powders. And 13 percent of women with ovarian cancer used genital deodorant sprays, compared with 9 percent in the control group, Cook said.

What's not clear is how the use of such products might be linked to the development of ovarian cancer.

"We have a real gap in our knowledge," Cook said. "It has been suggested that particles or fibers in these powder products can move up the reproductive tract and actually deposit on the ovaries. However, that's not been clearly established."

Elsewhere, researchers are examining pathological slides of ovarian tissue to see whether particles and fibers from the powders ended up on women's ovaries.

For every 100,000 women in western Washington, 16 are diagnosed with ovarian cancer each year. About 34 percent of the women survive for five years after diagnosis.

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## Indexing (details) Cite

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| People               | Cook, Linda                                                                                                                                                                           |
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### Ovarian cancer risk linked to powder, sprays: [Rockies Edition]

Peggy Andersen The Associated Press. *Denver Post* [Denver, Colo] 05 Mar 1997: A.07.

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SEATTLE - Women may increase their risk of ovarian cancer by using powder in their genital area, particularly in sprays, a study suggests.

The researchers cautioned the study did not consider how much powder the women used or exactly what was in it in some cases.

But they said that because the use of powder in the genital area is so prevalent - up to half of all women, by some estimates - that even a modest increase in risk could have a real effect on the incidence of ovarian cancer.

The study, from the Fred Hutchinson Cancer Research Center and the University of Washington, was reported in the March 1 issue of the American Journal of Epidemiology. It involved 313 white women in three western Washington counties, 20 to 79 years old, who were diagnosed with ovarian cancer in 1986 through 1988. They were compared with 422 women with no history of ovarian cancer.

The study looked at cornstarch, talcum powder, baby powder, deodorant powder and scented bath powder, and four ways of using it: in genital sprays, by direct application after bathing, by storing diaphragms in powder and by applying powder to sanitary napkins.

Women who used sprays were found to have a 90 percent increased risk of ovarian cancer, though the study noted that some sprays did not contain powder. The researchers raised the possibility that some unidentified chemical substances - and not the powder itself - may be at fault.

At least six other studies have found a similar elevation in risk, epidemiologist Linda Cook noted. But she said it would be premature to make any kind of health recommendation. "I certainly find the results of this study suggestive, but they're not conclusive."

Copyright Denver Post Mar 5, 1997

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| <b>Last updated</b>            | 2010-07-31                                                      |
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